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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
KALLIS, RUSSELL	
ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 05/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/928,412	KAWAOKA ET AL.	
	Examiner	Art Unit	
	Russell Kallis	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3,4 and 11-18* is/are pending in the application.

4a) Of the above claim(s) *13,17 and 18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3,4,11,12 and 14-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 August 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/282,164.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/14/01,7/10/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group II, Claims 3, 11-12 and 14 in Paper No. 2/17/2004 is acknowledged. The traversal is on the ground(s) that the reasons provided were inadequate to support a conclusion of patentable distinctness on page 2 of the response. This is not found persuasive because Applicant has not presented arguments indicating what was inadequate about the reasons presented in the restriction, namely that the effect of expressing the cDNA encoding a transcription factor controlling a phenylpropanoid biosynthesis pathway in sense orientation will have a different effect than expressing it in antisense orientation. Further, Claims 4, 15 and 16 are added to Group II as they were inadvertently omitted from the invention of Group II also drawn to a transformed plant cell and plant.

The requirement is still deemed proper and is therefore made FINAL.

Claims 3-4 and 11-18 are pending. Claims 13 and 17-18 are withdrawn. Claims 3-4, 11-12 and 14-16 are examined.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3-4, 11-12 and 14-16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to an isolated DNA which hybridizes under stringent conditions to a DNA having a nucleotide sequence which comprises SEQ ID NO: 1 and encodes a transcription factor controlling a phenylpropanoid biosynthesis pathway and a recombinant vector and plant cell and plant comprising said DNA.

Applicants describe SEQ ID NO: 1, isolated from a Tobacco library using a P-box double stranded 12-mer, encoding a transcription factor that controls a phenylpropanoid biosynthetic pathway (specification Example 1, pages 16-17).

Applicants do not describe any other isolated polynucleotide sequences that hybridize under stringent conditions to SEQ ID NO: 1 and which encode a transcription factor controlling a phenylpropanoid biosynthetic pathway.

The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. The court stated that, "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." *See University of California v. Eli Lilly and Co.*, 119 F.3d 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). Applicants fail to describe a representative number of polynucleotide sequences encoding a protein that hybridizes under stringent conditions to SEQ ID NO: 1 and which encodes a transcription factor controlling a phenylpropanoid biosynthesis pathway falling within the scope of the claimed genus of polynucleotides which hybridize to SEQ ID NO: 1. Applicants only describe a single cDNA (SEQ ID NO: 1). Furthermore, Applicants fail to describe structural features common to members of the claimed genus of

polynucleotides. Hence, Applicants fail to meet either prong of the two-prong test set forth by *Eli Lilly*. Furthermore, given the lack of description of the necessary elements essential for control of a phenylpropanoid biosynthetic pathway, it remains unclear what features identify a polynucleotide that encodes a protein controlling a phenylpropanoid biosynthetic pathway. Since the genus of polynucleotides that encode a protein controlling a phenylpropanoid biosynthetic pathway has not been described by specific structural features, the specification fails to provide an adequate written description to support the breath of the claims.

Sequences that hybridize with SEQ ID NO: 1 encompass naturally occurring allelic variants, mutants of phenylpropanoid biosynthesis pathway transcription factors, as well as sequences encoding proteins having no known control of a phenylpropanoid biosynthesis pathway, of which Applicant is not in possession. Accordingly, the specification fails to provide an adequate written description to support the genus of polynucleotides encompassed by the hybridization language as set forth in the claims. (See Written Description guidelines published in Federal Register/Vol. 66, No.4/Friday, January 5, 2001/Notices: p.1099-1111).

Claims 3-4, 11-12 and 14-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated DNA of SEQ ID NO: 1 encoding a transcription factor controlling a phenylpropanoid pathway in Tobacco and Tobacco plant cells and Tobacco plants transformed with a vector comprising an antisense DNA of SEQ ID NO: 1, does not reasonably provide enablement for an isolated DNA that hybridizes to SEQ ID NO: 1 and encodes a transcription factor controlling a phenylpropanoid biosynthesis pathway and plant cells and plants transformed with an antisense construct thereof. The specification does not

enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands,* 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

Applicant broadly claims an isolated DNA that hybridizes to SEQ ID NO: 1 encoding a transcription factor controlling a phenylpropanoid biosynthetic pathway.

Applicants describe SEQ ID NO: 1, isolated from a Tobacco library using a P-box double stranded 12-mer, encoding a transcription factor that controls a phenylpropanoid biosynthetic pathway (specification Example 1, pages 16-17).

The state of the art for isolating DNA fragments using stringent hybridization conditions is unpredictable because it does not always select for DNA fragments whose contiguous nucleotide sequence is the same or nearly the same as the probe. Fourgoux-Nicol et al (1999, Plant Molecular Biology 40: 857-872) teach the isolation of a 674bp fragment using a 497bp probe incorporating stringent hybridization conditions comprising three consecutive 30 minute rinses in 2X, 1X and 0.1X SSC with 0.1% SDS at 65°C (page 859, left column, 2nd paragraph). Fourgoux-Nicol et al also teach that the probe and isolated DNA fragment exhibited a number of

sequence differences comprising a 99bp insertion within the probe and a single nucleotide gap, while the DNA fragment contained 2 single nucleotide gaps and together the fragments contained 27 nucleotide mismatches. Taking into account the insertions, gaps and mismatches, the longest stretch of contiguous nucleotides to which the probe could hybridize consisted of 93bp of DNA (page 862, Figure 2) and thus, one could not easily predict the isolation of a DNA encoding a transcription factor based upon hybridization conditions.

The state of the art for manipulation of plant metabolism/phenotype using transgenes is highly unpredictable in any particular plant species where the DNA sequences required to affect that aspect of metabolism are not taught and would require using an orthologous DNA sequence. Even a careful consideration of the likely reduction in sequence identity or homology of the transgene or portions of the transgene to an uncharacterized and an endogenously expressed DNA sequence, could not reliably predict the interactions of the transgene and endogenous target DNA sequence and hence the phenotype from expression of a particular transgene or transgene portion cannot be reliably predicted when transformed into another species of plant (Wu K. *et al.*, Plant Physiology, 1997, Vol. 114, pp. 1421-1431; page 1430 column 1, lines 11-27 and last paragraph lines 5-9; and Applicant's specification on pages 2-4).

Based upon Applicant's limited guidance one cannot predict which embodiments would be operable and thus undue trial and error experimentation would be required by one of skill in the art to isolate and test the multitude of non-exemplified DNA sequences that hybridize to SEQ ID NO: 1 and to transform and screen a myriad of non-exemplified transformed plants from any species for the ability of any isolated DNA that hybridized to SEQ ID NO: 1 to encode a transcription factor that would control a phenylpropanoid biosynthetic pathway when

transformed into a plant cell or plant encompassed by the claims.

Given the unpredictability in the art as to which polynucleotide sequences that hybridize under stringent conditions to SEQ ID NO: 1 to encode a transcription factor controlling a phenylpropanoid biosynthesis pathway when transformed into any plant cell or plant; the breadth of the claims encompassing any polynucleotide sequence that hybridizes under stringent conditions to SEQ ID NO: 1; the lack of guidance in the examples of the specification or in the prior art as to which nucleotide sequences would control phenylpropanoid pathways in a transformed plant; and the undue trial and error experimentation required to practice the claimed invention, the invention is not enabled for the scope set forth in the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3-4, 11-12 and 14-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Tamagnone L. *et al.* The Plant Cell, February 1998, Vol. 10; pages 135-154.

Applicant broadly claims any nucleotide sequence that hybridizes to SEQ ID NO: 1 under unspecified hybridization conditions and any nucleotide sequence that hybridizes to SEQ ID NO: 1 under low stringency conditions at 55° C using 6X SSC salt buffer with no wash conditions recited in Claim 4.

Tamagnone teaches that isolated polynucleotides encoding MYB transcription factors from Antirrhinum repressed phenolic acid metabolism, a branch of phenylpropanoid metabolism,

and lignin biosynthesis in transgenic tobacco plants (see Abstract). Tamagnone also teaches Tobacco plants transformed with an antisense MYB construct (page 136, column 2 lines 6-10). Thus, the reference teaches all the limitations of Claims 3-4, 11-12 and 14-16.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 3-4, 11-12 and 14-16 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 and 6-8 of U.S. Patent No. 6,303,847. Although the conflicting claims are not identical, they are not patentably distinct from each other because the'847 Patent is drawn to SEQ ID NO: 1 isolated from Tobacco that encodes a transcription factor controlling a phenylpropanoid pathway and transformed plant cells and plants.

All Claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (571) 272-0798. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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May 11, 2004

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